Application No.: 10/602,838 Attorney Docket No.: 6423.404-US Page 2 of 8

Response to Office Action of February 6, 2009

AMENDMENTS TO THE CLAIMS:

The following Listing of Claims replaces all prior versions, and listings, of claims.

LISTING OF CLAIMS

1. (Currently Amended) A liquid, aqueous composition comprising:

(i) a factor VII polypeptide;

(ii) an agent suitable for keeping pH in the range of from about 5.5 to about 7.0;

(iii) a calcium salt in a concentration of at least 200 mM, such that the composition is

hypertonic;

wherein said composition has decreased formation of heavy chain fragments upon storage of said aqueous composition for 6 months at 2-8°C as compared with non-hypertonic compositions and wherein said factor VII polypeptide retains at least 50% of its initial biological activity upon storage

of said aqueous composition for 6 months at 2 8°C.

2. (Previously Amended) A composition according to claim 1, further comprising (iv) an ionic

strength modifying agent.

3. (Original) A composition according to claim 2, wherein the ionic strength modifying agent (iv) is

selected from the list of: a neutral salt, e.g., sodium chloride; an amino acid; or a small peptide, or a

mixture of at least two of said modifying agents.

4. (Original) A composition according to claim 3, wherein the ionic strength modifying agent (iv) is

sodium chloride.

5. (Cancelled).

6. (Original) A composition according to claim 2, wherein the agent (iv) is present in a concentration

of at least about 5 mM.

Application No.: 10/602,838 Attorney Docket No.: 6423.404-US Response to Office Action of February 6, 2009 Page 3 of 8

7. (Original) A composition according to claim 1, wherein the calcium salt is selected from the group consisting of: calcium chloride, calcium acetate, calcium gluconate, and calcium laevulate.

- 8. (Cancelled).
- 9. (Cancelled).
- 10. (Cancelled).
- 11. (Previously Amended) A composition according to claim 1, wherein the tonicity modifying agent (v) is selected from the group consisting of: a neutral salt; a monosaccharide; a disaccharide; polysaccharide; a sugar alcohol; an amino acid; a peptide, and a mixture of at least two of said modifying agents.
- 12. (Cancelled).
- 13. (Cancelled).
- 14. (Original) A composition according to claim 1, further comprising (vi) a non-ionic surfactant.
- 15. (Original) A composition according to claim 14, wherein the non-ionic surfactant is a polysorbate or a polyoxyethylene alkyl ether.
- 16. (Original) A composition according to claim 1, further comprising (vii) an antioxidant
- 17. (Previously Amended) A composition according to claim 16, wherein the antioxidant (vii) is selected from the group consisting of: L- or D-methionine, ascorbic acid, cysteine, homocysteine, gluthatione, cystine, and cystathionine.
- 18. (Original) A composition according to claim 17, wherein the antioxidant is L-methionine.

Application No.: 10/602,838 Attorney Docket No.: 6423.404-US Response to Office Action of February 6, 2009 Page 4 of 8

19. (Original) A composition according to claim 16, wherein the antioxidant is present in a

concentration of from about 0.1 to about 5.0 mg/ml.

20. (Cancelled).

21. (Previously Amended) A composition according to claim 1, wherein the agent suitable for

keeping pH in the range of from about 5.5 to about 7.0 is selected from the group consisting of acids

and salts of: citrate, acetate, histidine, malate, phosphate, tartaric acid, succinic acid, MES, HEPES,

Imidazol, TRIS, lactate, glycylglycin, PIPES, glycin, and a mixture of at least two of said agents.

22. (Original) A composition according to claim 21, wherein the concentration of the agent is from

about 1 mM to about 50 mM.

23. (Previously Amended) A composition according to claim 22, wherein the concentration of the

agent is about 10 mM.

24. (Original) A composition according to claim 1, further comprising (viii) a preservative selected

from the group consisting of phenol, benzyl alcohol, orto-cresol, meta-cresol, para-cresol, methyl

paraben, propyl paraben, benzalconium chloride, and benzaethonium chloride.

25. (Original) A composition according to claim 1, wherein said factor VII polypeptide is stable for

at least 6 months at 2-8°C.

26. (Original) A composition according to claim 1, wherein the factor VII polypeptide is

recombinantly made human factor VIIa.

27. (Cancelled).

28. (Cancelled).

Application No.: 10/602,838 Attorney Docket No.: 6423.404-US

Response to Office Action of February 6, 2009 Page 5 of 8

29. (Original) A composition according to claim 1, wherein the factor VII polypeptide is present in a

concentration of from about 0.1 mg/ml to about 10 mg/ml.

30. (Previously Amended) A method for preparing a liquid, aqueous composition of a factor VII

polypeptide, comprising the step of providing the factor VII polypeptide in a solution comprising (ii)

an agent suitable for keeping pH in the range of from about 5.5 to about 7.0; (iii) a calcium salt in a

concentration of at least 200 mM, such that the composition is hypertonic; wherein composition

retains at least 50% of its initial biological activity upon storage of said aqueous composition for 6

months at 2-8°C.

31. (Previously Amended) A method for treating a factor VII-responsive syndrome, the method

comprising administering to a subject in need thereof an effective amount of an aqueous liquid

composition comprising (i) a factor VII polypeptide, (ii) an agent suitable for keeping pH in the

range of from about 5.5 to about 7.0; (iii) a calcium salt in a concentration of at least 200 mM, such

that the composition is hypertonic; wherein said composition retains at least 50% of its initial

biological activity upon storage of said aqueous composition for 6 months at 2-8°C.

32. - 37. (Cancelled).